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|---|
| HUI, SAN MING R |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1617 | |

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Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. 10/017,273 | Applicant(s) NAYLOR ET AL. | |
|---|---|---|---|
| | Examiner San-ming Hui | Art Unit 1617 | |

*-- The MAILING DATE of this communication appears on the cover sheet with th correspondenc address --*

**Peri d f r Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *16 April 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *3-9,11,13-25 and 28-44* is/are pending in the application.

4a) Of the above claim(s) *11,17-23,25,28-32 and 39-43* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3-9,13-16,24,33-38 and 44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

## DETAILED ACTION

This application is a continuation-in-part of 09/895,367, filed June 29, 2001, which claims benefit of 60/265,358, filed 1/31/2001. This application is a continuation-in-part of 09/905,846, filed July 13, 2001, which claims benefit of 60/291,722, filed may 17, 2001.

The subject matter of the instant application is not disclosed in the 09/895,367. 09/895,367 only discloses the use of NPY inhibitor with NEP inhibitors for treating male erectile dysfunction. However, 09/895,367 does not disclose the method of how to screen the appropriate NPY inhibitors or NPY1 inhibitors in the treatment of male erectile dysfunction.

This application also claims benefit of United Kingdom 0030647.2, filed December 15, 2000; United Kingdom 0108730.3, filed April 6, 2001; United Kingdom 0109910.0 filed April 23, 2001. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

### *Election/Restrictions*

Applicant's election of the invention of Group I, claims 3-9, 13-16, 24, 33-38, and 44 in Paper No. 11 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Applicant's election of the specie PDE inhibitor in Paper No. 11 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the

restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 11,17-23, 25, 28-32, and 39-43 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 11.

The claims have been examined herein to the extent they read on the elected invention and species.

### *Claim Objections*

Claims 3-9, 13-16, 24, 33-38, and 44 are objected to because of the following informalities: the use of abbreviation such as "MED" is improper. Appropriate correction is required.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3-9, 13-16, 24, 33-38, and 44 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The instant claims are drawn to the "prevention" of male erectile dysfunction (hereinafter MED). The instant specification does not provide

information for one of skilled in the art to "prevent" MED in patients that are not suffered from it. The term "prevent" construed as an absolute prevention for MED. It is known in the art that the impotence has numerous etiologies such as alcoholism, neurogenic disorders, intrappsychic factors including bnormal fear of vagina, sexual guilt, depression, and fear of intamacy (See Merck Manual, 16th ed., 1992, page 1575 – 1576). The instant specification does not provide sufficient guidance as to how to keep the etiologies from being manifested into MED.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3-9, 13-16, 24, 33-38, and 44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The expression "inhibitor has no, or substantially no, activity towards endopeptidase NEP and/or angiotensin converting enzyme" in claim 4 renders the claim indefinite as to the degree of activity towards endopeptidase NEP and/or angiotensin converting enzyme. Therefore, it is not clear what inhibitors would be encompassed by the claim.

Claim 5 is not understood because it is not clear what the term "selective" referred to. Is it the NPY inhibitor being selective? Or the patient as selective? It is confusing.

The expression "NPYi when in use is selective for an NPY associated with male genitalia" recited in claim 13 renders the claims indefinite. It is not clear what NPY is considered as associated with male genitalia. Therefore, it is not clear what NPY inhibitors are encompassed by the claims.

The expression "NPYi that is capable of selectively increasing the intracavernosal pressure" in claim 15 renders the claim indefinite as to what NPY inhibitors are encompassed by the claims. What NPY inhibitors are considered as NP inhibitors that selectively "increase the intracavernosal pressure"? And what NPY inhibitors will not selectively "increase the intracavernosal pressure"? In other words, the metes and bounds of the claim are not defined.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 33 recites the broad

recitation "abnormal drink and food intake disorders", and the claim also recites "obesity, anorexia, bulimia and metabolic disorders" which is the narrower statement of the range/limitation.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 3-9, 13-16, 24, 33, and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hutchison et al. (WO 98/03492) and Gregor et al. (WO 98/07420).

Hutchison et al. teaches a new class of neuropeptide Y1 specific ligands. Hutchison et al. also teaches a method of treating disorders associated with an inappropriate stimulation of neuropeptide Y receptors, including diseases related to sexual dysfunction and reproductive disorders, and abnormal drink and food intake such a obesity, anorexia, bulimia, and metabolic disorders (See page 9, lines 6-9 and 26-28

in particular). Hutchison et al. teaches the composition comprising the Neuropeptide Y1 antagonist is useful for oral, topical, parenteral administration (See page 11, lines 3-4).

Gregor et al. teaches compound F50 of the instant application as regulators of NPY activity (See page 15 and abstract in particular). Gregor et al. further teaches that the compound is useful as feeding suppressant (See page 19, lines 3-5) Gregor et al. further teaches that these compositions, which possess vasodilating activities and are capable of beneficially affecting the reperfusion of ischemic organs, can be administered orally, topically and locally (See page 19, lines 3-5 and 11-20, in particular).

The references do not expressly teach the neuropeptide inhibitors can increase the intracavernosal pressure. The references do not teach the herein claimed timing of dosing (.e., before or during sexual arousal).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the neuropeptide Y inhibitors of Hutchison et al. or Gregor et al. in a method of treating MED by increasing the intracavernosal pressure.

One of ordinary skill in the art would have been motivated to the neuropeptide Y inhibitors of Hutchison et al. or Gregor et al. in a method of treating MED by increasing the intracavernosal pressure because the neuropeptide Y inhibitors of Hutchison et al. or Gregor et al. are known to be useful as increase the blood flow perfusion. Increasing blood perfusion in the male genitalia would cause the increase of intracavernosal pressure and thereby erection. Examiner notes that F50 is the exemplified neuropeptide Y inhibitors and therefore considered as possessing the herein claimed

characteristics (i.e., selective in NPY associated or located with male genitalia, having no, or substantially no, activity towards endopeptidase NEP and/or angiotensin converting enzyme of NPY inhibitor).

One of ordinary skill in the art would have been motivated to administer the NPY inhibitors of Hutchison and Gregor in the treatment of MED before or during sexual arousal. Optimization of dosage regimen is considered as within the purview of skilled artisan.

Claims 34-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hutchison et al. and Viagra monograph, June 1999.

Hutchison et al. teaches a new class of neuropeptide Y1 specific ligands. Hutchison et al. also teaches a method of treating disorders associated with an inappropriate stimulation of neuropeptide Y receptors, including diseases related to sexual dysfunction and reproductive disorders, and abnormal drink and food intake such a obesity, anorexia, bulimia, and metabolic disorders (See page 9, lines 6-9 and 26-28 in particular). Hutchison et al. teaches the composition comprising the Neuropeptide Y1 antagonist is useful for oral, topical, parenteral administration (See page 11, lines 3-4).

Viagra monograph teaches Viagra is a PDE 5 inhibitors useful for treating erectile dysfunction and can be administered orally (See page 2381, col. 3, Clinical Pharmacology Section; page 2384, Dosage and Administration Section).

The references do not expressly teach to employ both NPY inhibitor and PDE 5 inhibitor together in a method of treating MED.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ both NPY inhibitor and PDE 5 inhibitor together in a method of treating MED.

One of ordinary skill in the art would have been motivated to employ both NPY inhibitor and PDE 5 inhibitor together in a method of treating MED. It is known in the art that both NPY inhibitor and PDE 5 inhibitor are useful in treating MED individually. Therefore, combining two agents, which are known to be useful to treat MED, individually into method useful for the very same purpose is *prima facie* obvious (See *In re Kerkhoven* 205 USPQ 1069).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (703) 305-1002. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (703) 305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

San-ming Hui
Patent Examiner
Art Unit 1617
June 28, 2003